SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dicard® 200 mg Film Coated Tablets (Sacubitril / Valsartan)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Sacubitril 97.2 mg and Valsartan 102.8 mg.

3. PHARMACEUTICAL FORM

Film- coated tablet. Pink, circular, biconvex tablet, plain on both sides.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment of symptomatic chronic heart failure with reduced ejection fraction in adults and children aged 1 year and above.

4.2. Posology and method of administration

As detailed in the revised product information.

4.3. Contraindications

Hypersensitivity, concomitant ACE inhibitor use, history of angioedema, aliskiren use in diabetics, pregnancy (2nd–3rd trimester).

4.4. Special warnings and precautions for use

Risk of hypotension, renal impairment, hyperkalaemia, angioedema.

4.5. Interaction with other medicinal products

ACE inhibitors, aliskiren, statins, PDE- 5 inhibitors, lithium.

4.6. Fertility, pregnancy and lactation

Contraindicated in late pregnancy; not recommended during breastfeeding.

4.7. Effects on ability to drive and use machines

May cause dizziness or fatigue.

4.8. Undesirable effects

Hypotension, hyperkalaemia, renal impairment, dizziness, fatigue.

Reporting of suspected adverse reactions

Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

4.9. Overdose

Symptomatic management recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Angiotensin receptor neprilysin inhibitor.

5.2. Pharmacokinetic properties

Consistent with adult and paediatric data.

5.3. Preclinical safety data

No special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Microcrystalline cellulose, crospovidone, magnesium stearate, talc, colloidal silica.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Do not store above 30°C. Protect from light.

Store below 30°C.

6.5. Nature and contents of container

Aluminium/Aluminium blisters, pack of 30 tablets.

6.6. Special precautions for disposal

Dispose in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Cosmos Limited

Rangwe Road; Off Lunga Lunga Road, Industrial Area.

P. O. Box 41433, Gpo 00100 – Nairobi, Kenya

8. MARKETING AUTHORISATION NUMBER(S)

H2022/CTD8705/20160

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11.01.2022

10. DATE OF REVISION OF THE TEXT

11.01.2022